

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PRONOVA BIOPHARMA NORGE AS,)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No.
APOTEX CORP.,)	
)	
and)	
)	
APOTEX INC.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Pronova BioPharma Norge AS (“Pronova”), by way of Complaint against Defendants Apotex Corp. and Apotex Inc., (collectively “Apotex”) alleges as follows:

THE PARTIES

1. Pronova is a corporation organized and existing under the laws of Norway with its corporate headquarters at Vollsveien 6, 1366 Lysaker, Baerum, Norway. Pronova is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Apotex Corp. is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. Apotex Inc. is a corporation organized and existing under the laws of Canada,

having a principal place of business at 150 Signet Drive, Weston, Toronto, Ontario, Canada M9L 1T9.

NATURE OF THE ACTION

4. This is an action for infringement of U.S. Patent No. 5,502,077 (“the ’077 patent”) and U.S. Patent No. 5,656,667 (“the ’667 patent”), arising under the United States patent laws, Title 35, United States Code, §100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Apotex’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market generic pharmaceutical products (“Apotex’s generic products”).

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. Upon information and belief, this Court has jurisdiction over Apotex Corp. Upon information and belief, Apotex Corp. is incorporated in Delaware and directly, or indirectly, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Corp. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Apotex Corp’s products, including products manufactured by Apotex Inc, such as Apotex’s generic products. Apotex Corp. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

7. Upon information and belief, this Court has jurisdiction over Apotex Inc. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing and selling generic drugs. Upon information and belief, Apotex Inc. directly, or through its wholly-owned subsidiaries (primarily Apotex Corp.), manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Inc. purposefully has conducted and continues to conduct business in this judicial district, directly or indirectly, and this judicial district is a likely destination of products manufactured by Apotex Inc., such as Apotex's generic products. Apotex Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

8. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

9. The U.S. Patent and Trademark Office ("PTO") issued the '077 patent on March 26, 1996, entitled "Fatty Acid Composition." A copy of the '077 patent is attached as Exhibit A.

10. The '077 patent is assigned to Pronova. Pronova is the owner of the '077 patent as recorded by the PTO at Reel 019795, Frame 0594.

11. The '077 patent expires on March 26, 2013.

12. The '077 patent claims, *inter alia*, methods of using omega-3-acid ethyl esters.

13. The '077 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for New Drug Application ("NDA") No. 21-654, which the FDA approved on November 10, 2004.

14. Omega-3-acid ethyl esters manufactured by Pronova are sold in the United States under the trademark Lovaza®.

15. Upon information and belief, Apotex filed with the FDA ANDA No. 90-973 under Section 505(j) of the Act, 21 U.S.C. § 355(j).

16. Upon information and belief, Apotex's ANDA No. 90-973 seeks FDA approval to engage in the commercial manufacture, use or sale in the United States of generic products containing omega-3-acid ethyl esters (i.e., Apotex's generic products).

17. On March 23, 2009, Pronova received a letter from William A. Rakoczy, on behalf of Apotex, dated March 20, 2009, purporting to be a Notice of Certification for ANDA No. 90-973 ("Apotex's 90-973 letter") under Section 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95.

18. Apotex's 90-973 letter alleges that Apotex's generic products for which it seeks approval contain omega-3-acid ethyl esters.

19. Upon information and belief, Apotex's generic products will, if approved and marketed, infringe at least one claim of the '077 patent.

20. Under 35 U.S.C. § 271(e)(2)(A), Apotex Corp. and Apotex Inc. have infringed at least one claim of the '077 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-973 seeking approval for the commercial marketing of Apotex's generic products before the expiration of the '077 patent.

21. Upon information and belief, the actions relating to Apotex's ANDA No. 90-973 complained of herein were done at the direction of or with the authorization, cooperation, participation or assistance of Apotex Corp. and Apotex Inc., and for the benefit of each.

SECOND COUNT FOR PATENT INFRINGEMENT

22. Pronova realleges, and incorporates in full herein, paragraphs 9-21.

23. The PTO issued the '667 patent on August 12, 1997, entitled "Fatty Acid Composition." A copy of the '667 patent is attached as Exhibit B.

24. The '667 patent is assigned to Pronova. Pronova is the owner of the '667 patent as recorded by the PTO at Reel 019795, Frame 0594.

25. The '667 patent expires on April 10, 2017.

26. The '667 patent claims, *inter alia*, omega-3-acid ethyl ester compositions and methods of using omega-3-acid ethyl esters.

27. The '667 patent is listed in the Orange Book for NDA No. 21-654.

28. Upon information and belief, Apotex's generic products will, if approved and marketed, infringe at least one claim of the '667 patent.

29. Under 35 U.S.C. § 271(e)(2)(A), Apotex Corp. and Apotex Inc. have infringed at least one claim of the '667 patent by submitting, or causing to be submitted to the FDA, ANDA No. 90-973 seeking approval for the commercial marketing of Apotex's generic products before the expiration of the '667 patent.

30. Upon information and belief, the actions relating to Apotex's ANDA No. 90-973 complained of herein were done at the direction of or with the authorization, cooperation, participation or assistance of Apotex Corp. and Apotex Inc., and for the benefit of each.

WHEREFORE, Plaintiff Pronova respectfully requests that the Court enter judgment in its favor and against Defendants Apotex Inc. and Apotex Corp. (collectively “Apotex”) on the patent infringement claims set forth above and respectfully requests that this Court:

- 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim of the '077 patent through Apotex's submission of ANDA No. 90-973 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic products before expiration of the '077 patent;
- 2) order that the effective date of any approval by the FDA of Apotex's generic products be a date that is not earlier than the expiration of the '077 patent, or such later date as the Court may determine;
- 3) enjoin Apotex from the commercial manufacture, use, import, offer for sale and/or sale of Apotex's generic products until the expiration of the '077 patent, or such later date as the Court may determine;
- 4) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex's ANDA No. 90-973 until expiration of the '077 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim of the '667 patent through Apotex's submission of ANDA No. 90-973 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic products before expiration of the '667 patent;

- 6) order that the effective date of any approval by the FDA of Apotex's generic products be a date that is not earlier than the expiration of the '667 patent, or such later date as the Court may determine;
- 7) enjoin Apotex from the commercial manufacture, use, import, offer for sale and/or sale of Apotex's generic products until the expiration of the '667 patent, or such later date as the Court may determine;
- 8) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex's ANDA No. 90-973 until expiration of the '667 patent;
- 9) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Pronova costs, expenses and disbursements in this action, including reasonable attorney fees; and
- 10) award Pronova such further additional relief as this Court deems just and proper.

ASHBY & GEDDES

/s/ John G. Day

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